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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/738,540 | 12/14/2000 | Wync Pun Lee | P1795R1 | 2012 |

9157 7590 05/11/2004

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EXAMINER

HADDAD, MAHER M

| | |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1644

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|--|--------------------------------------|-----------------------------------|--|
| <p align="center">Office Action Summary</p> | Application No. 09/738,540 | Applicant(s) LEE ET AL. | |
| | Examiner Maher M. Haddad | Art Unit 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6 and 18-25 is/are pending in the application.
- 4a) Of the above claim(s) 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6, 18-20 and 24-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 3/16/04, is acknowledged.
2. Claims 1, 6 and 18-25 are pending.
3. Claims 21-23 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.
4. Claims 1, 6, 18-20 and 24-25 are under consideration in the instant application.
5. In view of the amendment filed on 3/16/04, only the following rejections are remained.
6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 6, 18-19 and 24-25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,690,933, in view of U.S. Patent No. 6,306,820 (of Record) as is evidenced by the known fact disclosed in the specification on page 16, line 5 and page 17, lines 4-5 for the same reasons set forth in the previous Office Action mailed 9/12/03.

Applicant's arguments, filed 03/16/03, have been fully considered, but have not been found convincing.

Applicant argues that the '933 patent fails to specifically disclose a method of treating rheumatoid arthritis with an anti-CD11a antibody and an immunosuppressive agent let alone a TNF- α antagonist that is TNF- α receptor - IgG Fc fusion protein as recited in the present claims. Applicant further argues that '820 patent fails to teach or suggest any anti-LFA-1 antagonist let alone anti-CD11a antibody in combination therapy with a TNF- α antagonist in a method of treating RA. Applicant contends in conjunction with case law that without some suggestion in the cited references to modify or combine the teachings of the references, the Office has not established a prima facie case of obviousness. Applicant further contends that obviousness

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cannot be predicted on hindsight reconstruction of the invention using the Applicant's disclosure as a guide.

Contrary to applicant arguments the '933 patent teaches the use of anti-CD11a mAb in conjunction with other immunosuppressive agents to treat autoimmune diseases including RA. Further, the '820 patent teaches the ability of TNFbp products or sTNFR Fc(s) and methotrexate to act synergistically in the treatment of various symptoms associated with TNF-mediated diseases, including acute and chronic inflammation such as rheumatic diseases. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the TNF- α antagonist in combination with methotrexate taught by the '820 patent with the immunosuppressive agent taught by the '933 patent in a method of treating rheumatoid arthritis. Given the '820 patent teachings the ability of TNF- α antagonists and methotrexate to act synergistically in the treatment of chronic inflammation such as rheumatic disease, one of ordinary skill in the art at the time the invention was made would have been motivated to use them in a method of treating rheumatoid arthritis because the combined treatment with TNF- α antagonist and methotrexate has the advantage of achieving the same result with a lower dose or less frequent administration of methotrexate, thereby reducing any toxic effect.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. In re McLaughlin , 170 USPQ 209 (CCPA 1971).

8. Claim 20 stands rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,690,933, in view of U.S. Patent No. 6,306,820 (of Record) as is evidenced by the known fact disclosed in the specification on page 16, line 5 and page 17, lines 4-5 as applied to claims 1, 6, 18-19 and 24-25 above, and further in view of Owens *et al* (1994) for the same reasons set forth in the previous Office Action mailed 9/12/03.

Applicant's arguments, filed 03/16/03, have been fully considered, but have not been found convincing.

Applicant contends that Owens reference while discussing humanized antibodies does not overcome the inadequacies of Cobbold ('933 patent) and Bendele ('820 patent) to achieve the claimed invention.

Given the absence of additional rebuttal to the outstanding rejections of record in applicant's amendment; the rejections are maintained for the reasons of record.

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9. No claim is allowed.


10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher Haddad, Ph.D.
Patent Examiner
April 29, 2004


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600